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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,756	06/24/2005	Jean-Pierre Cougoulic	0510-1114	7167

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EXAMINER	
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ART UNIT	PAPER NUMBER
1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,756	COUGOULIC, JEAN-PIERRE	
	Examiner	Art Unit	
	MICHAEL PEPITONE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-24, 26-27, and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Cougoulic (US 5,872,159).

Regarding claims 21-22 and 39-40 : Cougoulic teaches a material for medical or veterinary use designed for the execution of endo-bone implants, bone prostheses [instant claim 40], and dental implants [instant claim 39] (1:5-12), wherein the material is in the form of a molded part made of a biocompatible thermoplastic polymer {binder} containing at least one compound for adding calcium or phosphorous (1:35-62; 2:56-60; 3:20-4:20), wherein the material comprises a thermoplastic polymer in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite [instant claim 22] (1:55-2:3; 2:61-3:14).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a surface with emerging crystallized calcium phosphate, would inherently be achieved by a composition

with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Regarding claims 23-24: Cougoulic teaches the binder is a thermoplastic polymer [instant claim 23], specifically polyetheretherketone (PEEK) [instant claim 24] (2:23-43).

Regarding claim 26: Cougoulic teaches TiO_2 (2:44-50).

Regarding claim 27: Cougoulic teaches chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and metallic oxide (TiO_2) (2:61-3:14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159 as applied to claim 21 above, and in further view of Ellingsen *et al.* (US 2002/0111694).

Regarding claim 25: Cougoulic teaches the basic claimed composition [as set forth above with respect to claim 21].

Cougoulic does not teach cellulose as a binder. However, Ellingsen *et al.* teaches medical prosthetic devices and implants (bone and dental) comprising cellulose as a biopolymer (¶ 2, 9, and 19). Cougoulic and Ellingsen *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined cellulose, as taught by Ellingsen *et al.* in the invention of Cougoulic, and would have been motivated to do so since Ellingsen *et al.* suggests that cellulose provides tissue resilience, strength, rigidity, and integrity of the extra-cellular matrix (¶ 21).

Claims 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Mills *et al.* (US 6,482,584).

Regarding claims 28-38: Cougoulic teaches a method for preparing a material for medical or veterinary use (1:5-12), wherein the material is prepared by mixing a mixture comprising a thermoplastic polymer in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and subjected to molding operations (1:35-2:3; 2:61-3:14; 3:43-4:15).

Cougoulic does not teach surface pickling or decontamination operations on the molded material, nor packaging aseptically of the decontaminated material [instant claim 28]. However, Mills *et al.* teaches a method of cleaning/sterilizing implants, as well sterile packaging of the implant (1:5-14; 3:65-4:11; 14:34-55), comprising subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which can undergo

{elevated} temperature and pressure cycles {autoclave} [instant claim 28] (4:14-65), and which permits sonication of the contents (4:52-54; 6:49-58; 8:14-51) [instant claim 29-31 and 38]. The surface treatment includes solutions of: HCl [instant claim 32] (14:5-21, Table II (J)), acetone [instant claim 33] (14:5-21, Table II (J)); hydrogen peroxide [instant claim 34] (4:14-18), sodium hypochlorite [instant claim 35] (14:5-12), Betadine or isopropanol {decontaminating product} [instant claim 36] (4:14-18; 14:5-21), and sterile water [instant claim 37] (11:28-33, Tables I and II). Cougoulic and Mills *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents, and sterile packaging of the implant, as taught by Mills *et al.* in the invention of Cougoulic, and would have been motivated to do so since Mills *et al.* suggests that such processes provide penetrating sterilization of the implant (4: 65-5:14; 8:14-51).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a surface with emerging crystallized calcium phosphate, would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Mills *et al.* (US 6,482,584).

Regarding claim 41: Cougoulic teaches a method for preparing a material for medical or veterinary use (1:5-12), wherein the material is prepared by mixing a mixture comprising a thermoplastic polymer in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and subjected to molding operations (1:35-2:3; 2:61-3:14; 3:43-4:15).

Cougoulic does not teach surface pickling or decontamination operations on the molded material, nor packaging aseptically of the decontaminated material. However, Mills *et al.* teaches a method of cleaning/sterilizing implants, as well sterile packaging of the implant (1:5-14; 3:65-4:11; 14:34-55), comprising subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which can undergo {elevated} temperature and pressure cycles {autoclave} (4:14-65), wherein the chamber permits sonication of the contents (4:52-54; 6:49-58; 8:14-51). The surface treatment includes solutions of: HCl (14:5-21, Table II (J)), acetone (14:5-21, Table II (J)); hydrogen peroxide (4:14-18), sodium hypochlorite (14:5-12), Betadine or isopropanol {decontaminating product}(4:14-18; 14:5-21), and sterile water (11:28-33, Tables I and II) [i.e. a process of pressure cycling or oscillation, employing a variety of cleaning and sterilization solutions (8:15-51, Tables I-II) {sterilization via autoclave} with concurrent ultrasonic bombardment {surface pickling}, wherein the process steps can be repeated (4:35-37; 8:44-46), and the cleaning fluid is removed to waste under positive pressure

and the implant is rinsed under positive pressure and the rinse fluid is removed under positive pressure (11:24-35); subsequently the implant material is packaged in a sterile environment (14:33-55)]. Cougoulic and Mills *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents, and sterile packaging of the implant, as taught by Mills *et al.* in the invention of Cougoulic, and would have been motivated to do so since Mills *et al.* suggests that such processes provide penetrating sterilization of the implant (4: 65-5:14; 8:14-51).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a surface with emerging crystallized calcium phosphate, would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Response to Arguments

Applicant's arguments filed 2/24/09 have been fully considered but they are not persuasive. The rejection of claims 21-24, 26-27, and 39-40 based upon Cougoulic (US

5,872,159) is maintained for reason of record and following response. Cougoulic (US '159) discloses a material for medical or veterinary use designed for the execution of endo-bone implants, bone prostheses, and dental implants, wherein the material is in the form of a molded part made of a biocompatible thermoplastic polymer {binder} [PEEK] in an amount of at least 65 weight% and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate and calcium hydroxyapatite (1:55-2:3; 2:61-3:14; 3:45-4:47). As claimed, the material of Cougoulic (US '159) would inherently provide emerging crystallized calcium phosphate, as the reference teaches all of the claimed reagents and the material was prepared under similar conditions {see above}.

The Declaration under 37 CFR 1.132 filed 2/24/09 is insufficient to overcome the rejection of claims 21-24, 26-27, and 39-40 based upon Cougoulic (US '159) as set forth in the last Office action because: as claimed, claim 1 requires a molded piecework made of 65-90 wt% of a polymer biocompatible binder and 10-35 wt% calcium phosphate. Cougoulic (US '159) clearly discloses such materials (3:45-4:47) as noted in Applicant's Declaration (pg. 3, ln. 4-13). While the material according to invention is of the same composition, the inventive material was exposed to surface pickling/decontamination treatments and then autoclave sterilization whereas the prior art material was only sterilized via autoclave {Applicant's Declaration (pg. 4, ln. 1-2)}. Since the surface pickling/decontamination treatments are not recited in the claims, and the claims are directed towards a product which is anticipated by Cougoulic (US '159) the rejection is maintained. Furthermore, "products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or

claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) [see MPEP 2112.01]. The Declaration is insufficient for the reasons set forth above to overcome the rejection.

Mills *et al.* (US 6,482,584) was relied on for subjecting implants to an oscillation of pressure and temperature in the presence of various cleaning solutions in a chamber {autoclave} which permits sonication of the contents, as well as sterile packaging of the implant, as such processes provide penetrating sterilization of the implant (3:65-4:11; 4:14-65; 8:14-51; 11:24-45) [i.e. a process of pressure cycling or oscillation, employing a variety of cleaning and sterilization solutions (8:30-51, Tables I-II) {sterilization via autoclave} with concurrent ultrasonic bombardment {surface pickling}, wherein the process steps can be repeated (4:35-37; 8:44-46), and the cleaning fluid is removed to waste under positive pressure and the implant is rinsed under positive pressure and the rinse fluid is removed under positive pressure (11:24-35); subsequently the implant material is packaged in a sterile environment (14:33-55)].

Ellingsen *et al.* (US 2002/0111694) was relied on for the incorporation of a cellulose binder in medical implants (¶ 2, 9, and 19), as cellulose provides tissue resilience, strength, rigidity, and integrity of the extra-cellular matrix (¶ 21).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pepitone whose telephone number is 571-270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MFP
15-May-09

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796